IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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SERIAL NO.: 10/521,922 ART UNIT: 1645

FILED: August 29, 2005 EXAMINER: Gangle, B. J.

TITLE: SPECIFIC ISOTYPE ANTIBODIES OF SECRETION-EXCRETION ANTI-ANTIGENS OF *LEISHMANIA SP* OF PROMASTIGOTE OR AMASTIGOTE FORMS, etc...

Amendment A: REMARKS

Upon entry of the present amendments, Claims 1-9 have been canceled and Claims 10-15 have been substituted therefor. Reconsideration of the rejections, in light of the forgoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of more clearly distinguishing the present invention from the prior art and for the purpose of placing the claims into a condition for allowance.

In the Office Action, it was indicated that Claims 5-7 and 9 were rejected under 35 U.S.C. §101 as a claimed recitation of a use. Claims 1-4 and 9 were rejected under 35 U.S.C. §101 as being drawn to a product of nature. Claims 1-4 and 8 were also rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and as failing to comply with the enablement requirement. Claims 1-9 are also rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 1-4 and 8 were rejected under 35 U.S.C. § 102(b) as being anticipated by the Deplazes reference. Claims 1-4 and 8 were also rejected under 35 U.S.C. § 102(b) as being anticipated by the Afrin reference. Claims 1-4 and 8 were further rejected under 35 U.S.C. § 102(b) as being anticipated by the Sartori reference. Objections to the drawings and specification have also been made with respect to reference numerals and grammatical errors. Formality

objections to the claim language are included as well. Corrected drawings and specification amendments were requested.

As an overview to the present reply, Applicant has amended the claims from the direct French translation submitted in the original filing. The proper claim formalities may aid the Examiner in considering the patentable subject matter of the present invention. The composition claims have been presented as Claims 10-11, corresponding to original Claims 1-4 and 8. The method claims have been presented as Claims 12-15, corresponding to original Claims 5-7 and 9. Applicant has also amended the drawings and specification to correct the formalities objected to by the Examiner.

In reply to the Office Action, Applicant has extensively amended the independent claims so as to more accurately claim the composition and methods of the present invention. The independent composition claim now incorporates the subject matter of original Claims 2-4. Applicant has entered these amendments in response to the rejections under 35 U.S.C. §101 and 35 U.S.C. §112, first and second paragraphs. The claim language is no longer drawn to a product of nature, and the limitations now sufficiently describe and define the subject matter of the composition. Applicant respectfully contends that recitation of a specific epitope of a protein sequence, requiring a sequence identification, is not necessary due to the several limitations on the claimed immunoglobulins. The specified conditions, properties and organism are sufficient to enable one skilled in the art to produce the claimed composition.

With further regard to the rejection under 35 U.S.C. §112, second paragraph, Applicant respectfully contends that "IgG2 and corresponding sub-classes" are now sufficiently defined in Claim 10. The term "classes" has been canceled, and "sub-classes" are not yet known to those

skilled in the art. Any specific sub-class cannot be named at this time. Applicant further contends that "excretion-secretion" and "antigent" and "Protein Surface Antigens" are well-known terms of the art considered to be proteins. Applicant argues that it is understood that excretion and secretion are equivalent, and that such terms are used for descriptive purposes for the proteins in the supernatants of a culture medium.

Furthermore, Applicant states that "carboxyterminal part" is sufficiently described in the specification to mean the last part of the protein immunogen molecule, after repeated patterns rich in Leucine, as defined in prior art. The subject matter of Claim 8 has been re-presented as dependent Claim 11, and the "effector" term has been replaced with "markers" so as to more clearly define the immunoglobulins in the immunotherapy context. Applicant respectfully contends that the new format and language of the claims have placed the application into a condition for allowance.

In response to the rejections based upon prior art, Applicant notes that the Deplazes reference, Afrin reference and Sartori reference disclose IgG2 antibodies in dogs infected with L. infantum, in mouse immunized with antigens of L. donovani, and in hamster infected with L. donovani, respectively. The present invention is a composition of IgG2 antibodies specific to the carboxyterminal part of an antigen in dogs immunized with antigens of the promastigote forms and amastigote forms of L. infantum. More precisely, these immunoglobulin proteins are specific to a "cryptic" or immunologically silent epitope located in the carboxyterminal part of that secreted antigen in the dogs. These antibodies induced in dogs immunized with secretion-excretion antigens do not exist in naturally infected mammals with leishmanies. Thus, the composition of the present invention is not disclosed by the proteins of the Deplazes reference and the Sartori reference. Those prior art references relate to only the IgG proteins of naturally leishmanian animals (see paragraphs

12 to 18).

The Afrin reference describes the humoral and cell-mediated immune responses in hamsters and mice, immunized with an antigenic extract of a parasite alone or encapsulated in liposomes. These preparations produce antibodies of any class IgG, IgA, and IgM, and preferably induce a response of IgG1 antibodies specific to the Th2 type of immune response. In contrast, the present invention describes antibodies against the carboxyterminal part of an antigen not described in the Afrin reference. These antibodies of IgG2 isotype are selectively generated in dogs immunized with excretion-secretion antigens, of the Th1 type immune response. Thus, the antibodies of the invention have a specificity different of that those disclosed in the Afrin reference. Furthermore, it is very risky and dangerous to extend the results obtained in mouse and hamster for dogs, especially considering that dogs are the only natural host to the infection with L infantum and L. chagasi. It is unlikely that the disclosure of the mice and hamster antigens cross species with different effects for the specific antigen.

With regard to the method claims, the methods now include the limitations of the composition of Claim 10. The method of use are specifically limited to the application and steps related to the claimed composition of immunoglobulins. The proper claim language format has attempted to remove the simple recitation of a use.

The specification has been amended to remove the references to drawings. No drawings were associated with the priority PCT application. Such figures are not required to understand the scope of the invention presented, although such figures are available from the original French priority document. In any case, those figures are not presented in the present application as new matter. No new drawings are presented. Additionally, the proper notation of the trademark term is not included

throughout the specification.

Based upon the foregoing analysis, Applicant respectfully contends that independent Claim 10 is now in proper condition for allowance. Additionally, those claims which are dependent upon this independent claim should also be in condition for allowance. Reconsideration of the rejections and allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

A Petition for Extension of Time is filed concurrently herewith. The requisite fee is also included with this Petition.

Respectfully submitted,

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Date

/Andrew W. Chu/

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